UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,413	02/27/2002	Avraham J. Domb	Q63391	7369

23579 7590 03/10/2006

PATREA L. PABST
PABST PATENT GROUP LLP
400 COLONY SQUARE
SUITE 1200
ATLANTA, GA 30361

EXAMINER	
FLOOD, MICHELE C	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,413	DOMB ET AL.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-12,14-17,19-26 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-12,14-17,19-26 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on December 24, 2005. Further acknowledgment is made of Applicant's cancellation of Claim 18.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6-12, 14-17, 19-26 and 38 are under examination.

Claim Rejections - 35 USC § 112

Claims 1-4, 6-12, 14-17, 19-26 and 38, as amended, remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising (a) a therapeutically effective amount of at least one agent selected form the group of herbal agents and drugs, wherein the herbal agents are selected from the group consisting of bioactive herbs, herbal extracts, tinctures, essential oils, and mixtures thereof or, and the drugs are selected from the group consisting of analgesics, anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial drugs, antiulcer drugs, peptides and combinations thereof; and (b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa, does not reasonably provide enablement for a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue

comprising (a) a therapeutically effective amount of at least one homeopathic active agent and (b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, as broadly claimed by Applicant.

The claims are directed to a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising (a) a therapeutically effective active amount of at least one agent selected from the group of herbal and homoeopathic active agents and drugs, wherein the herbal and homeopathic agents are selected from the group consisting of bioactive herbs, herbal extracts, tinctures, essential oils, and mixtures thereof, and the drugs are selected from the group consisting of analgesics, anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial drugs, antiulcer drugs, peptides and combinations thereof, and (b) a pharmaceutically acceptable solid bioadhesive carrier comprising a mucoadhesive synthetic polycarboxylic acid polymer in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of

the prior art; (d) the level of one of ordinary skill in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation added to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

While the specification has reasonably demonstrated a method of making and using a solid, self-bioadhesive composition for topical application that adheres to mucosal tissue comprising a therapeutically effective amount of at least one agent selected from the group consisting of herbal agents and drugs and a pharmaceutically acceptable solid bioadhesive carrier comprising a mucoadhesive synthetic polycarboxylic acid polymer in a claim designated percent based on the weight of the composition in a form suitable for administration and adhesion to the oral mucosa, the specification is not enabled for the claim-designated composition comprising a therapeutically effective amount of homeopathic amounts. The specification is non-enabling for the claim designated composition as the specification does not provide guidance as to how to identify any and all ingredients used in the making of an composition comprising a therapeutically effective active amount of an agent, wherein the agent is a homeopathic agent selected from the group consisting of bioactive herbs, herbal extracts, tinctures, essential oils and mixtures thereof, how to determine such amounts as defined therein, and how to determine the effective therapeutic amounts of a homeopathic agent for use in the making of the claim-designated composition. While the specification has reasonably demonstrated a composition comprising a

therapeutically effective amount of an herbal bioactive agent or a drug present in a therapeutically effective amount, other than the mere description for the general preparation of a homeopathic medicine for the treatment of a bacterial infections in [0141] to [0142], the specification does not adequately describe the source of the ingredients, the amounts of the ingredients or the therapeutically effective amounts of the ingredients to result the effect for incorporating a homeopathic agent selected from the group consisting of bioactive herbs, herbal extracts, tinctures, essential oils and mixtures thereof to provide for the making and/or use thereof or the claim-designated composition. At the time the invention was filed, the state of the art did not fully support the incorporation of homeopathic agents or homeopathic amounts of bioactive agents into the making of pharmaceutical compositions that were intended for the purpose of administration to subjects, particularly humans, to provide a therapeutic result in the treatment of disease conditions. *See* the 1999 quackwatch.com website reference entitled "Homeopathy: The Ultimate Fake" by Dr. Stephan Barrett. Even by Applicant's own admission, it would at least appear that the determination for the administration of a therapeutically effective amount of a homeopathic agent is at best a matter of trial and error to provide effective means for treating mucosal disorders suffered by humans, as set forth in the disclosure at [0137]. Hence, it is highly unlikely that the skilled artisan at the time the invention was made would be able to make and/or use the claim-designated composition comprising a therapeutically effective amount of homeopathic agents comprising any and all of the other instantly claimed ingredients, "wherein the agent is present in a homeopathic amount, which is less than a therapeutically effective

amount". Moreover, the Office notes that with the filing of the Appeal Brief, Applicant has readily submitted "Exhibit B" (entitled "Questions and Answers About Homeopathy") that teaches, "Various explanations have been proposed as to how homeopathy might work. However, none of these explanations have been scientifically verified", on page 1, last two lines. On page 15 of "Exhibit B", under "8. What has scientific research found out about whether homeopathy works" also teaches, "The results of individual, controlled clinical trials of homeopathy have been contradictory. In some trials, homeopathy appeared to be no more helpful than a placebo; In other studies, some benefits were greater than one would expect from a placebo [citations omitted]."

In order to enable the skilled artisan to practice the invention as claimed, Applicant would have to describe the amounts of each of the instantly claimed homeopathic agents intended to provide the claim-designated composition comprising a therapeutically effect amount of the homeopathic agent. Given the insufficient guidance in the specification as to what ingredients or amounts of ingredients encompass a therapeutically effective amount of a homeopathic agent from each of the claim-designated ingredients of any and all bioactive herbs, herbal extracts, tinctures, essential oils and mixtures thereof, the lack of working examples, the lack of correlative working examples, and the state of the art at the time the specification was originally filed, the claims would require an undue amount of experimentation without a predictable degree of success on the part of the skilled artisan.

Accordingly, it would take undue experimentation without a reasonable expectation of success for the skilled artisan to identify any and all ingredients used in

the making of an solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising a therapeutically effective amount of a homeopathic agent comprising any and all bioactive herbs, herbal extracts, tinctures, essential oils and mixtures thereof, or how to determine such amounts as defined therein, as broadly claimed by Applicant.

Claims 15-17 and 19--21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

The metes and bounds of Claim 15 are rendered vague and indefinite by the phrase, "further comprising a non-herbal active agent", because it is uncertain as to the subject matter Applicant intends to direct the instantly claimed invention, since the drafting of the claim language of Claim 1 at present already includes the possibility of the claim designated composition to include more than one active agent that is a non-herbal active agent, namely a homeopathic agent and/or a drug. The lack of clarity renders the claim ambiguous.

Claim 19 recites the limitation "the active agent", in line 1. There is a lack of clear antecedent basis for this limitation in the claim.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Objections

There is an apparent typographical error in Claim 1, line 4. Applicant may overcome the objection by deleting "agent".

There is an apparent omission of a transitional phrase in Claim 1, line 7. Applicant may overcome the objection by adding wherein, before "the drugs" in line 7.

Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. For instance, Claim 15 is objected to because the phrase, "further comprising a non-herbal active agent", fails to further limit the subject matter of Claim 1, the claim from which it depends. For instance, the aforementioned claim limitation is readable on the "drugs" comprising the claim-designated composition of Claim 1.

Each of the cited claim objections are newly applied as necessitated by amendment of the claims.

Claim Rejections - 35 USC § 102

Claims 1-4, 6, 15-17, 22-24, 26, 27 and 38, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al. (A). Newly applied as necessitated by amendment.

Applicant claims a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising: (a) a therapeutically effective amount of at least one agent selected from the group consisting of herbal and homeopathic active agents and drugs, wherein the herbal and homeopathic agents are selected from the group consisting of bioactive herbs, herbal extracts, tinctures, essential oils, and mixtures thereof; and wherein the drugs are selected from the group consisting of analgesics, anti-inflammatories, antihistamines, antigens, steroids other than anti-inflammatories, vitamins, enzymes, antipyretics, antimalarial, antiulcer drugs, peptides, and combinations thereof; and (b) a pharmaceutically acceptable solid bioadhesive carrier comprising a mucoadhesive synthetic polycarboxylic acid polymer in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosal. Applicant further claims the solid composition of claim 1, wherein the composition is in the form of a disc of 2 to 15 mm diameter and 0.4 to 2.3 mm thick that adheres to the oral mucosal for at least 30 minutes; and, wherein the composition is in the form of a disc 5 to 11 mm in diameter and 1 to 2 mm thick with tissue adherence of at least 1 hour; wherein the herbal and homeopathic agents are selected from a recited Markush group as set forth in Claim 6; wherein the herbal and homeopathic agents are selected from a recited Markush group as set forth in Claim 6; wherein the solid bioadhesive carrier is selected from the group of a crosslinked synthetic polycarboxylic acid polymer and mixtures thereof; wherein the polymer is a copolymer or one or more polymers selected from the group consisting of a recited Markush group as set forth in Claim 23; and, wherein the composition has a

surface are ranging from about 0.4 to about 3 cm^2. Applicant further claims the composition of claim 1 further comprising an excipient selected from the group consisting of fillers, tableting excipients, lubricants, enhancers, flavors, taste-masking agents, pH controlling compounds, dyes, stabilizers, enzymes inhibitors, and mixtures thereof. Applicant further claims the composition of claim 22, wherein the solid bioadhesive carrier is selected from polyacyrlic polymers crosslinked with a polymer selected from the group consisting of polyalkenyl polyether, carboxymethylcellulose, hydroxymethylcellulose, and mixtures thereof. Applicant further claims the composition of claim 1, further comprising a non-herbal active agent.

Inoue teaches a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising a therapeutically effective amount of a drug and a mixture of polymers of polycarboxylic acid and/or a polycarboxylic acid anhydride and a vinyl acetate polymer that adheres to the oral mucosa. The amount of the polycarboxylic acid polymer comprising the referenced composition is an amount of 40% by weight of the total composition. *See* Column 3, line 24 to Column 4, line 31; and, Column 5, line 66 to Column 6, line 21. Drugs incorporated into the making of the Inoue' composition include bioactive herbals or extracts thereof (for example, glycyrrhizin, hinokitiol, menthol, tannin, berberine, *etc.*); steroids, vitamins; anti-inflammatories (for example, glycyrrhizin, an extract of *Glycerrhiza*, *etc.*); enzymes; and non-herbal active agents (for example, mepivacaine, tetracaine, dibucaine and dexamethasone). Excipients, such as dyes and flavoring matters, may further comprise the Inoue' composition. Column 10, lines 5-14. In Column 8, lines 45-61, Inoue

teaches that the referenced composition has a thickness from 10 to 150 μm; a width ranging from 7 to 15mm; and, a diameter ranging from 5 mm to 20 mm. In Column 11, lines 3-10, Inoue teaches that the residency time of the compositions in oral mucosal tissue is generally 3 to 4 hours. In Column 14, lines 49-62, Inoue teaches the referenced composition wherein the bioadhesive carrier comprises polyvinyl acetate, diisopropanolamine and a carboxyvinyl; and a therapeutic effective amount of *Lithospermi* Radix extract, which is in the form of a disc and having a diameter of 10mm.

The reference anticipates the claimed subject matter.

Claims 1-3, 15-17, 22-24, 26, 27 and 38, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Nagai et al. (B). Newly applied as necessitated by amendment.

Applicant's claimed invention was set forth above.

Nagai teaches a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising: (a) a therapeutically effective amount of a drug (for example, anti-inflammatory agents, fungicides, anesthetics, the enzymes lysozyme hydrochloride and dextranase, chlorohexidine, quaternary ammonium salts, hydrocortisone, vitamins and benzocaine, as set forth in Column 5, line 57 to Column 6, line 17) and; (b) about 50 to about 95% by weight of a cellulose ether (*See* Column 4, lines 46-68.) and about 50 to about 5% of a homo- or copolymer of carboxylic acid, such as a polycarboxylic acid (S*ee* Column 5, lines 18-21.). Excipients, which may further

comprise the composition taught by Nagai include fillers, tableting agents, lubricants, flavors, taste-masking agents. See Column 6, lines 24-39. In Column 7, lines 2-11, Nagai teaches that the referenced composition has a residency time for 4 hours in the oral mucosal cavity. In Column 18, lines 23-44, Nagai teaches discs having a thickness of 1.4 mm and a diameter having a thickness of 10.mm comprising 50% of a polycarboxylic copolymer (Carbopol 934) and 50% of hydroproxycellulose and triamcinolone acetonide.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

Claims 1-4, 6-12, 15-17, 19, 22-27 and 38, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. (A*) in view of Iyer et al. (C*) and Friedman et al. (D*) with evidence provided by Lawless (U). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claims 1-4, 15-17, 22-24, 26, 27 and 38 was set forth above. Applicant further claims the composition of claim 1, wherein the herbal agent is an essential oil selected from a recited Markush group; and further comprising a salt selected from the group consisting of $MgBr_2$, NaCl, KCl, and mixtures thereof.

The teachings of Inoue are set forth above. Inoue teaches the instantly claimed composition except for wherein the herbal active agent is an essential oil; wherein the herbal active agent of claim 6 comprises at least one monoterpene with three saturations, wherein the essential oil is a natural or synthetic mixture consisting of

myrcene, a-pinene, b-pinene, and sabinene characterized in that at least 60% by weight of the mixture is limonene, and wherein said monoterpenes with three unsaturations is of citrus oil selected from the group consisting of lemon, pomelo and citron; and wherein the composition further comprises a salt selected from the group consisting of $MgBr_2$, NaCl, KCl, and mixtures thereof . However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the instantly claimed ingredients to the composition taught by Inoue to provide the instantly claimed invention because at the time the invention was made it was known in the art that the claim-designated agents were useful in the making of topical compositions for the treatment of oral mucosal tissue, as evidenced by the teachings of Iyer and Friedman. Firstly, Iyer teaches various herbal active agents, such as essential plant oils and herbal extracts have antimicrobial activity that are useful as therapeutic agents such as in oral hygiene products. For example, Iyer teaches antimicrobial compositions comprising at least two antimicrobial agents, agent A and agent B, which exhibit reduce MIC values relative to the MIC for the agents making up the combination measured alone. For example, in Column 3, lines 11-26, Iyer teaches that agent A and agent B are selected from the group consisting of berberine, cedarwood oil, chloramphenicol, citral, citronella oil, cocamidopropyl dimethylglycine, *Glycyrrhiza glabra* extract, hinokitol, juicy fruit basil oil, juniper berries oil, lemon basil oil, lemon oil, and *Rosmarinus officinalis* oil. Secondly, Friedman teaches a combination of an herbal extract and an essential oil which exerts prolonged antifungal activity on mucosal membranes. The herbal extracts include material selected from the group consisting of Plantago, Hypericum, Echinacea,

Baptisia, Calendula, Myrrh, Phytolocca, Salvia, Catechu black, Coneflower, Krameria, Tsuga, Rosmarinus, Styrax, Crataegus, Glycerrhiza, Angelica, Krameria, Matricaria, Mallow, Propolis (beehive material), and Sage; and the essential oils are selected from cinnamon oil, cajeput oil, citronella oil, eucalyptus oil, fennel oil, geranium oil, lavender oil, lemon oil, spearmint oil, myrte oil, oregano oil, pine oil, rosemary oil, sarriette oil, thyme oil, and tea-tree oil (see Column 1, lines 6-10; Column 2, lines 38-59; and claims). In Column 5, lines 9-39, Friedman further teaches that the herbal extracts are in the form of a tincture of botanical materials. In Figures 1 and 2, Friedman shows that the referenced compositions have prolonged activity against *Aspergillus niger* and *Candida albicans*. In Column 4, lines 18-37, Friedman teaches that the compositions can be used to combat fungal infection of mucosal organs and the oral cavity. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the instantly claimed ingredients to the composition taught by Inoue to provide the claimed invention because Iyer, like Inoue teaches that the active agents of his invention can be used in the making of therapeutic oral hygiene products for the treatment of stomatitis, as well as for growth control of bacteria, such as *Actinomyces viscosus, Campylobacter rectus, Fusobacterium nucleatum, Porphyromonas gingivalis, Streptococcus mutans* and *Streptococcus mutans* (see Column 3, lines 28-38 and 47-51), as well as for the treatment of ; and Friedman teaches that the compositions of his invention have strong antibacterial activity and anti-inflammatory activity, as well as antifungal activity, which can be used in the making of oral products, and which can be used in the treatment of

disease conditions such as *Herpes zoster* and *Herpes simplex* infections, dental ulcers, stomatitis, aphthous ulcers, and abscesses (see Column 4, lines 31-37; Column 8, lines 36-42; Column 9, lines 66-67 to Column 10, lines 1-4; and Column 10, lines 30-51). One of ordinary skill in the art at the time the invention was made would have been further motivated and one would have had a high expectation of success to add the antimicrobial compositions taught by Iyer to the bioadhesive composition taught by Inoue to provide the claimed invention because Iyer teaches in Table 14 that the combination of the essential oil of lemon (which comprises 70% limonene, myrcene, pinenes and sabinene, as evidenced by the teaching of Lawless) in combination with an antimicrobial Agent B results in a significant decrease in the MIC value against various microorganisms which cause oral or periodontal disease. Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed methods because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references clearly indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed

composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by that reference.

According, the claimed the invention was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood

MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
March 2, 2006